

# DRUG EXPERIENCE REPORTS: THEIR USE AND ABUSE IN LITIGATION

*Instead of being liberally admitted in evidence, DERs should be used only to show notice that a reasonable manufacturer should have heeded*

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THE ADMISSIBILITY of drug experience reports in drug product liability litigation is anything but clear. DERs have been used to prove causation, as the basis of expert testimony, or to show notice to the manufacturer. Some courts, however, have severely limited or barred their admissibility. While DERs are of critical importance to public safety in providing an early warning system of potential side effects of drugs after marketing, their use in the courtroom is controversial.

This article explores the uses of drug experience reports in the courtroom and the objections to those uses. Also discussed is the potential impact of the Bendectin cases, which have held that for public health reasons a plaintiff's proof of causation must be of sufficient certainty to protect the drug manufacturer from undeserved liability. At this higher level of proof, the anecdotal drug experience report is not relevant to the causation issue.

As to notice of potential side effects, courts must recognize that, even if not preemptive, the Food and Drug Administration regulations place tight controls on the warnings and contraindications that drug manufacturers issue. Courts should find a notice of defect only when the information received would lead the responsible manufacturer to change its warnings in accordance with federal regulations. At this standard, anecdotal DERs are not relevant to show that the manufacturer received notice of a dangerous side effect sufficient to issue new warnings. When those side effects are proved to a degree at which the manufacturer becomes obligated under federal regulation to alert the medical practitioner, liability for failure to warn should arise.

DERs may still have a place in the courtroom to show constructive notice or to establish punitive damages when, through the mishandling of DERs or blind ignorance to the

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trends they suggest, a manufacturer fails to investigate and pursue scientific leads.

## POTENTIAL USES AND MISUSES OF DERs

Drug experience reports, which are submitted voluntarily to the drug manufacturer from various sources, can be useful to plaintiffs in product liability litigation. Sometimes they are admitted as evidence that a drug caused a reaction,<sup>1</sup> or individual or compiled DERs are allowed to serve as the basis for expert testimony about causation without being admitted into evidence.<sup>2</sup> More often, DERs are admitted as evidence that a manufacturer had notice of a dangerous side effect,<sup>3</sup> or that a manufacturer had constructive notice because the DERs

1. See e.g., *In re Richardson Merrell Inc. Bendectin Prods. Liab. Litig.*, 624 F.Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989) (plaintiffs used 96 summarized DERs as causation evidence) [hereinafter *Bendectin*]; *Barson v. E.R. Squibb & Sons Inc.*, 682 P.2d 832 (Utah 1984) (summary of DERs admitted for causation evidence).

2. See, e.g., *Bendectin*, *supra* note 1; *Barson*, *supra* note 1; *Cebenka v. Upjohn*, 80C-AP-67 (Del. Super.Ct., May 27, 1988) (Lexis No. 179).

3. See, e.g., *Hermes v. Pfizer Inc.*, 848 F.2d 66 (5th Cir. 1988).

should have led it to recognize an emerging association.<sup>4</sup> A manufacturer's mishandling of DERS may serve as evidence of fraud and cover-up, giving support to punitive damage claims.<sup>5</sup> Other courts refuse to admit DERS or allow experts to rely on them as the basis of their opinions.<sup>6</sup>

The admission of DERS into evidence or their use by experts pose evidentiary obstacles. DERS are hearsay—out-of-court statements offered for the truth of the matter asserted in them—when plaintiffs offer them for purposes other than notice. Their admissibility also raises relevancy objections.

When DERS are offered to show causation, the mere temporality between the ingestion of the drug and the reaction does not prove the relation of the two events. Despite the potential that DERS may come from unreliable sources, that they may represent mere coincidental events rather than causation and that they lack scientific credibility, they may have a prejudicial effect on a jury, especially when they are cumulative.

When DERS are the basis of expert opinion about causation, they must overcome the objection that experts would not rely on anecdotal reporting to form an opinion on causation. While Federal Rule of Evidence 703 has been regarded as a low hurdle, it is not meaningless, and courts are divided on whether these anecdotal reports should be relied on by experts.

DERS are used to show notice of a dangerous side effect, supporting the claim of failure to warn adequately. Arguably, this is the most appropriate use of DERS. It seems logical that a reasonable and prudent drug manufacturer that receives reports of injuries associated with

its drug would change the warnings to alert prescribing physicians to that potential danger. Drug manufacturers are subject, however, to FDA regulations that define the manufacturer's responsibility to issue warnings and bar the issuance of warnings based on speculation and unconfirmed data.

Finally, evidence of the manufacturer's handling of DERS—that is, the manner in which it keeps its records them, makes full and timely filings to the FDA, and the vigor with which he pursues potential leads in uncovering side effects—is used to establish constructive notice of a danger in the absence of actual notice. Evidence of mishandling of DERS also may be the basis for punitive damage claims.<sup>7</sup>

#### DRUG EXPERIENCE REPORTING

Since 1962 the Food and Drug Administration has required drug manufacturers in the United States to report to it adverse drug reactions known to them. An adverse drug experience is "any adverse event associated with the use of a drug in humans, whether or not considered drug-related."<sup>8</sup> The manufacturer may learn of adverse drug reactions from many sources, including scientific and medical literature, post-marketing studies and spontaneous reports. When new and unforeseen side effects from marketed drugs become apparent, new product information issued by the manufacturer must incorporate those discoveries. FDA regulations expressly provide that "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."<sup>9</sup> The FDA requires that manufactur-

4. See, e.g., *Skill v. Martinez*, 91 F.R.D. 498, 511 (D. N.J.), *aff'd*, 677 F.2d 368 (3d Cir. 1981) (where manufacturer failed to keep tabulations of strokes, smoking and contraceptive use, jury could conclude manufacturer had notice from adverse reaction reports).

5. See, e.g., *Koller v. Richardson-Merrell Inc., Prod. Liab. Rep. (CCH)* ¶ 9583 (D. D.C. 1983).

6. See, e.g., *Richardson v. Richardson Merrell Inc.*, 649 F.Supp. 799 (D. D.C. 1986), *aff'd*, 857 F.2d 823 (1988), *cert. denied*, 110 S.Ct. 218 (1989); *Hagaman v. Merrell Dow Pharmaceuticals Inc.*, No. 84-2202-S (D. Kan., June 26, 1987) (Lexis No. 6124).

7. See *Stanton v. Astra*, 718 F.2d 553 (3d Cir. 1983) (violation of FDA regulations on reporting DERS is negligence per se).

8. 21 C.F.R. § 314.80(a).

9. 21 C.F.R. § 201.57(e) (emphasis supplied).

Manufacturers have argued that FDA regulation of both drug approval and drug labeling preempts private tort actions. Courts have not embraced the contention but generally have looked to the FDA to provide a minimum standard for warnings. See, e.g., *Hurley v. Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176 n.2 (5th Cir. 1988) (listing other cases); *Skill*, 91 F.R.D. at 508; *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Barson*, 682 P.2d at 836.

In addition, 21 C.F.R. § 314.70(c)(2) provides that a manufacturer may strengthen its warning beyond the FDA-approved warning. See Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 HARV. L. REV. 773, 785 (1990) (urging compromise position that preemption of tort claims applies if court finds FDA "made a reasonable judgment regarding the marketing and labeling of the medication"). See also Preuss, *Fed-*

ers issue contraindications only to "known hazards and not theoretical possibilities."<sup>10</sup>

The spontaneous reporting system that generates DERs relies on voluntary notification to the drug manufacturer or to the FDA by physicians, pharmacists and other health care providers. Oral or written reports of adverse reactions also come from consumers or from health care providers through company salesmen. The FDA regulations expressly provide that the submission of these reports by the health care provider to the manufacturer or the manufacturer's submission of the reports to the FDA does not constitute an admission that the drug caused or contributed to the medical condition reported.<sup>11</sup> In fact, a study of causality should not be done before submitting drug experience reports, as that would delay or impede reporting needlessly.<sup>12</sup>

The spontaneous reporting system is regarded as an "early warning system,"<sup>13</sup> and its success depends on the free flow of information to the manufacturer and the FDA.

The efficiency of the spontaneous reporting system in uncovering newly discovered side effects and adverse reactions is weakened by underutilization, which has been attributed to health care providers'

complacency, often resulting from the mistaken belief that only safe drugs are allowed onto the

market; fear of involvement in litigation or of an investigation of prescribing habits; guilt feelings about damage which they may have caused to their patients; ambition to collect and publish a personal series of cases; ignorance about what should be reported, how to report, and the value of reporting; diffidence to reporting mere suspicions' and indifference to their responsibility to contribute to the general body of knowledge about the effects of drug treatment.<sup>14</sup>

Underutilization of the DER reporting system impedes the timely discovery of side effects and makes DERs less effective as an early warning system. In litigation, however, the inappropriate filing of DERs and their potential inaccuracy should be more alarming to courts than underreporting. Some adverse reaction reports made to drug manufacturers may be an attempt at exculpation by health care providers, and others are filed by plaintiffs' attorneys as a preliminary step in litigation.<sup>15</sup>

After receiving a drug experience report, the drug manufacturer usually responds by a follow-up questionnaire directed to the party filing the report and inquiring about the patient, the medical history and other relevant circumstances surrounding the use of the drug. The manufacturer is required to investigate and assemble a file on each report. Sometimes the follow-up information is incomplete, the follow-up questionnaire is not returned or the re-

*eral Preemption of State Tort Actions: When and How*, 57 DEF. COUNS. J. 434, 438 (1990) (FDA labeling requirements do not preempt or define the bounds of common law duty to warn; there is no direct conflict between compliance with FDA regulations and common law tort liability); Denmark, *Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects*, 40 CASE W. RES. L. REV. 413, 431, citing Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 236 (1986) (bare legal right to make a warning more strict than FDA requires may be illusory for manufacturer whose livelihood may depend significantly on maintaining FDA's good will).

10. 21 C.F.R. § 201.57(d). A contraindication is defined as including "those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other conditions, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction.

11. 21 C.F.R. § 314.80(1).

12. Pearson & Kennedy, *Adverse Drug Reactions and the Food and Drug Administration*, 4 J. PHARMACY PRAC. 206, 211 (1989) [hereinafter *Adverse Drug Reactions*].

13. See Hagaman, *supra* note 6 (DERs only intended

use is as "early warning method" of detecting whether additional research is indicated for specific drug). See generally 7 AM. JUR. PROOF OF FACTS, *Injuries from Drugs*, §§ 1-11 (1990).

14. 7 AM. JUR. PROOF OF FACTS, *supra* note 13, at § 2.

15. Richardson-Merrell Inc. v. Koller, 472 U.S. 424 (1985), deciding whether disqualification of counsel in a civil case is subject to an immediate appeal as a final judgment, describes in detail the saga of DERs filed for purposes unintended by the designers of the reporting system. The plaintiffs' attorneys prepared and submitted DERs of other Bendectin users they represented and attempted to use those DERs at the Koller trial. The trial court ruled that it would not admit DERs submitted to the FDA more than one year after the birth of the Koller child, thus excluding 14 that had been offered by the plaintiffs' attorney. Later he provided the DERs to the *Washington Post*, which published an article discussing the exclusion of the DERs. This publicity, as well as an accusation that the attorneys had attempted to induce a fraudulent statement from their own employee, who accused them of filing a fraudulent suit, resulted in the delay of the trial and the disqualification of one of plaintiffs' law firms on the ground of misconduct.

See Cosgrove v. Merrell Dow Pharmaceuticals, 117 Idaho 470, 788 P.2d 1293, 1298 (1989). See also Green, *The Use of Drug Experience Reports in Drug Product Liability Litigation*, PERS. INJ. REV. 855, 862-63 (1989).

porter no longer has access to the patient. The manufacturer has no control over variables such as the time lapse between the reaction, the reporting and the follow-up, the availability of the subject or the quality of the reporter. These variables negatively effect the uniformity and reliability of DERs. Some DER files contain information about thoroughly investigated reactions, while others consist of no more than initial, sketchy reports.<sup>16</sup>

#### DERs AND CAUSATION

##### A. Bendectin Legacy and Proof of Causation

The trend in the most recent Bendectin drug product liability cases has been to require evidence of "statistically significant epidemiological proof" to demonstrate causation.<sup>17</sup> This position may reduce the potential usefulness of DERs as proof of causation.

Bendectin was a morning sickness drug prescribed to some pregnant women beginning in 1956. In the 1970s public concern arose over its teratogenic effect. Thousands of claims were made against Merrell Dow, the drug's manufacturer, alleging birth deformities arising from its use during pregnancy. While it is now generally concluded that Bendectin has no teratogenic effect during pregnancy,<sup>18</sup> the lawsuits took their toll. One court commented:

While Merrell Dow prevailed in the most

prominent of the trials arising out of these numerous cases, . . . it has also had large verdicts entered against it in other suits, though most of these have been reversed on appeal or overturned on a motion for judgment n.o.v. As a result of escalating insurance and litigation costs resulting from these cases, and decreased use of Bendectin flowing from the controversy surrounding its safety, Merrell Dow has ceased production of Bendectin.<sup>19</sup>

Plaintiffs in the many Bendectin cases relied on the testimony of the same few experts and studies. Both the nature and the sufficiency of the plaintiffs' causation evidence was vigorously challenged by Merrell Dow, and courts began to question the scientific methods employed by the experts in forming opinions as to Bendectin's teratogenicity.

In *Brock v. Merrell Dow Pharmaceutical Inc.*<sup>20</sup> the Fifth Circuit recognized the difficulty of weighing conflicting scientific evidence and announced a new standard as to the sufficiency of plaintiffs' causation evidence in drug cases:

We find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case. . . .

Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiologic proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning and statistical significance of studies presented by both sides.<sup>21</sup>

16. See Scott & Greig, *Medical Product and Drug Causation: How to Prove It and Defend Against It*, 56 DEF. COUNS. J. 270, 271 (1989) (although each DER is generally investigated by manufacturer and reported to FDA, frequently there is no way to verify accuracy or acquire more complete information) [hereinafter *Medical Product and Drug Causation*]. Compilations of DERs also are maintained, and they may suggest areas of needed study on unforeseen side effects. See *Adverse Drug Reactions*, *supra* note 12, at 211.

17. *Brock v. Merrell Dow Pharmaceutical Inc.*, 874 F.2d 307, modified and *aff'd en banc*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S.Ct. 1511 (1990). See also Richardson, 857 F.2d at 827 ("reasonable medical certainty").

18. DeLuca v. Merrell Dow Pharmaceutical Inc., 911 F.2d 941 (3d Cir. 1990), summarizes the Bendectin studies and case law and states (at 946) that "the great weight of scientific opinion, as is evidenced by the FDA committee results, sides with the view that Bendectin use does not increase the risk of having a child with birth defects." See also *Lynch v. Merrell-Nat'l Labs*, 830 F.2d 1190, 1194 (1st Cir. 1987), in which the court declared, "We face, then, a situation . . . in which . . . world-wide scientific investigations of Bendectin have produced no evidence establishing that Bendectin causes limb reduction, and in which the ir-

relevance of Bendectin to the incidence of limb defects has been demonstrated." See also Richardson, 649 F.Supp. at 803 ("now nearly universal scientific consensus that Bendectin has not been shown to be a teratogenic").

19. DeLuca, 911 F.2d at 943. The notable contrary case is *Oxendine v. Merrell Dow Pharmaceuticals Inc.*, 506 A.2d 1100 (D.C. 1986), *later proceeding*, 563 A.2d 330 (1989), *cert. denied*, 110 S.Ct. 1121 (1990), which overturned the lower court's judgment n.o.v. and reinstated a \$750,000 verdict for the plaintiff. In the later proceedings Merrell Dow attempted to win a new trial based on the plaintiff's expert's misrepresentations, but the court found that the misrepresentation could have been discovered prior to trial had Merrell exercised diligence, and that since the new evidence went only to impeachment, it could not form the basis for granting a new trial. 563 A.2d at 337.

20. *Supra*, note 17.

21. 874 at 167 (emphasis added). See also *In re Swine Flu Immunization Prods. Liab. Litig.*, 508 F.Supp. 897 (D. Colo. 1981), *aff'd sub. nom.* *Lima v. United States*, 708 F.2d 502 (10th Cir. 1983) (when plaintiff offered expert and anecdotal reports to prove reaction, court said "theories advanced by the experts . . . are speculative and are not generally supported in the medical literature"); *Zeck v. United States*, 559 F.Supp. 1345 (S.D.), *aff'd*, 720 F.2d 534 (8th Cir. 1983) (expert opinion supported by letters to edi-

The *Brock* court was particularly cognizant of competing public health tensions at the root of drug product liability litigation. It noted its concern that science has an inherent inability to pinpoint causation of a particular birth defect, an inability that could lead to inconsistent verdicts in essentially identical cases. The resulting uncertainty of outcome of litigation could cause manufacturers to withdraw potentially useful drugs from the market, and the fear of tort liability could impair the availability of useful drugs. Therefore, the court concluded, the sufficiency standard for causation proof must be high enough that it will guard against potentially capricious results.

An alternative approach, employed by other courts, has led to a result similar to that in *Brock*. These courts considered the admissibility rather than the sufficiency of the causation evidence. Several courts denied admission to plaintiffs' experts' testimony by relying on Federal Rule of Evidence 703, which provides: "The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived or made known to him at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence."

In both *Lynch v. Merrell-National Laboratories*<sup>22</sup> and *Richardson by Richardson v. Richardson-Merrell Inc.*,<sup>23</sup> the courts held that the plaintiffs' evidence that Bendectin was a teratogen was not only insufficient but also inadmissible because the overwhelming weight of scientific studies and peer reviewed literature concluded there is no statistically significant association between Bendectin and birth defects. The causation evidence was based on in vivo and in vitro animal studies, studies of "analogous" chemicals and "reanalyzed" epidemiological studies in which the results of a prior study were reanalyzed by using a different control group (Down's syndrome children). The reanalyzed study was not published or refereed. In *Lynch* the court said, "A new study coming to a different conclusion and challenging the consensus would be admissible evidence. Without such a study there is nothing on which expert opinion on Bendectin as a cause may be based."<sup>24</sup>

Courts struggling with either the admissibility or sufficiency of causation evidence in drug

liability cases often confront those issues in the context of the admissibility of DERs. Plaintiffs offer them as evidence of causation, arguing that the ingestion of the drug caused others to suffer similar injury, ergo, the plaintiff's injury was caused by the drug. The flaw in this logic is that the DERs offer no proof that the drug caused the reaction reported in a DER or that a particular plaintiff's injury and that in the DER are similar.

### B. Relevancy of DERs to Causation

The FDA encourages the voluntary submission of drug experience reports without asking for any evidence of causation. The early warning system would be less effective if health care providers withheld their suspicions and reported only reactions they could demonstrate scientifically. Reporters often are physicians, pharmacists or patients with limited experience with a drug. They do not observe patterns of reactions, only isolated events. Even a compilation of DERS does not rise to epidemiological proof; only studies that control for variables can establish causation proof.

The reporting of a drug reaction is largely the result of an injury temporal to the drug use. A DER generated because of a temporal reaction and offered as evidence of a causal link between the drug and the injury may represent nothing more than coincidental injury to an unknown third party. Gerald Faich, Direc-

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tors in medical journals of anecdotal reports of blood disorder reaction to swine flu vaccine to establish theory of causation insufficient as matter of law).

The Fifth Circuit reads its own *Brock* decision narrowly, possibly limiting the holding to drug products. In *Christopherson v. Allied-Signal Corp.*, 902 F.2d 362, 367, *reh'g granted en banc*, 914 F.2d 66 (5th Cir. 1990), a case involving workplace exposure to possible carcinogens, the court specifically declined to hold that "epidemiological proof is a necessary element in all toxic tort cases." See Klein, *Expert Testimony in Pharmaceutical Product Liability Actions*, 45 FOOD DRUG COSM. L.J. 393, 411 n.86 (1990). 22. 830 F.2d 1190 (1st Cir. 1987).

23. *Supra* note 6. See also *In re "Agent Orange" Prods. Liab. Litig.*, 611 F.Supp. 1223, 1249 (E.D. N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988) (as to causation in toxic torts, "courts are particularly wary of unfounded expert opinion").

24. 830 F.2d at 1194. *Accord Richardson*, 857 F.2d at 832; *Ealy v. Richardson-Merrell*, 897 F.2d 1159, 1163-64 (D.C. Cir. 1990), *cert. denied*, 111 S.Ct. 370 (1990); *Whelan v. Merrell Dow Pharmaceuticals*, Civ. No. 83-3108 (D. D.C., Aug. 30, 1990) (Lexis No. 11504). *But see Longmore v. Merrell Dow Pharmaceuticals*, 737 F.Supp 1117 (D.C. Idaho 1990) (refusing summary judgment on similar facts).

tor of the Office of Epidemiology and Biostatistics at the FDA, stated:

Despite their usefulness, one or even many reports of adverse reactions often do not provide sufficient information to confirm that a drug caused the reaction. A reaction may be caused by the suspect drug, another drug that a patient is taking, or the underlying diseases for which the drug was prescribed; it may also be entirely coincidental. Thus, adverse reaction monitoring should be viewed primarily as a means for identifying potential problems. Confounding is particularly likely when the drug exposure and the outcome are relatively common. In the case of doxylamine-pyridoxine (Bendectin), for example, there were large numbers of reports of congenital defects associated with exposure to the drug, simply because there was widespread use of the drug during pregnancy; the coincidental, non-causal nature of the association appears to have been demonstrated.<sup>25</sup>

While courts consistently have held that a mere temporal association does not establish causation,<sup>26</sup> they disagree whether DERs are relevant evidence to prove causation. In *In re Richardson Merrell Inc. Bendectin Products Liability Litigation*,<sup>27</sup> the manufacturer was granted judgment n.o.v., and the plaintiff appealed, claiming that the court had been too restrictive in refusing to admit 1,200 DERs. The Sixth Circuit affirmed, noting without criticism that 96 summarized DERs had been admitted and that several experts specifically described and relied on approximately a dozen DERs. In *Barson v. E.R. Squibb & Sons Inc.*<sup>28</sup> the Utah Supreme Court admitted an exhibit summarizing DERs to show causation.

Neither *Richardson Merrell* nor *Barson*, however, clearly stands for the proposition that

DERs are relevant evidence. In *Richardson-Merrell* the plaintiffs were raising the limited issue of admissibility on appeal. In *Barson* the defendant failed to make timely objection and raised a hearsay objection only on appeal. Thus, neither court squarely faced the relevance issue. These cases suggest that DERs can be evidence reasonably relied on by testifying experts who may find that they are relevant to establish causation, although they are not admitted into evidence for that purpose.

In *Hagaman v. Merrell Dow Pharmaceutical Inc.* the federal district court in Kansas held that DERs are not relevant evidence of causation because they represent nothing more than coincidence. The court said:

... DER's are an unscientific sample of experiences at best. It appears uncontroverted that their primary usefulness is as a red flag mechanism that could, in certain instances, tip off the drug manufacturers and the medical community that a certain drug may have some contraindications. Plaintiffs cannot seriously disagree with the proposition that the mere fact that a woman, or any number of women for that matter, took Bendectin during pregnancy and delivered a child with a birth defect does not establish causation. ... Therefore, plaintiffs' proof of causation will have to be supported by something other than unreliable reports of the coincidence of Bendectin and birth defects.<sup>29</sup>

This perspective ensures that the defendant will not be confronted with prejudicial evidence suggesting to a lay jury that a causal connection exists where none has been proved scientifically. The DER collection process does not ensure that each DER represents a thoroughly investigated complaint, the collection of complaints does not prove a causal link and the process contains its own biases. Therefore, the exclusion of this evidence may best serve the truth-seeking process.

### C. DERs Face Hearsay Objection

When DERs are offered as causation evidence, they represent hearsay because they are "offered to prove the truth of the matter asserted," within the meaning of Federal Rule of Evidence 801. Plaintiffs assert that the drug caused the reaction reported in the DERs, that the plaintiffs' reaction was sufficiently similar to those described in the DERS and that the

25. *Special Report: Adverse-Drug-Reaction Monitoring*, 314 NEW ENG. J. MED. 1589, 1591 (June 12, 1986).

26. See, e.g., *Heyman v. United States*, 506 F.Supp 1145, 1149 (S.D. Fla. 1981), in which the court said, "A mere temporal relation between any event and an illness does not demonstrate any causal connection between the two events. To demonstrate such a connection, statistical studies must be conducted; otherwise the temporal relationship may be simply the result of chance." See also *Saxe v. United States*, 577 F.Supp. 135 (N.D. Ohio 1983); *Peterson v. United States*, 569 F.Supp. 676 (D. Idaho 1983).

27. 624 F.Supp. 1212 (S.D. Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989).

28. 682 P.2d 832 (Utah 1984).

29. *Supra* note 6.

jury can infer the drug caused their reactions.

DERs represent multiple levels of hearsay. The reporter may be a physician, attorney or pharmacist, for example, who is merely relaying information provided by a patient, client or consumer. In addition, the reports often are transcribed by the manufacturer to the proper form as required by the FDA, and ultimately the files are maintained by the FDA. In order to be admissible, DERs must fit within one of the hearsay exceptions.

In *Muilenberg v. Upjohn Co.*<sup>30</sup> the Michigan Court of Appeals considered whether DERs maintained by Upjohn constituted "records of regularly conducted activit[ies]," so as to come within the exception of Michigan Evidence Rule 803(6), which is identical to Federal Rule 803(6). The court concluded that the DER documents satisfied neither the letter nor the spirit of that exception:

There is nothing to conclusively determine the time lapse between the doctor's discoveries and the recording of them. Whether or not the contents of the document were recorded at or near the time of the reported event is left to speculation. Moreover, Upjohn did not keep a record of the reactions to the drug "in the regular course of business," as the term is used in the court rule. The company does not draft the reports. It is dependent on information from the doctors. The document was nothing more than a compilation of outside information which the defendant had received.<sup>31</sup>

The court went on to liken DERs to surveys that are "routinely excluded as being nothing more than a compilation of hearsay." DERs also can be likened to accident reports filed by witness bystanders under no duty to file a report. The unreliable nature of DERs and the lack of control that the manufacturer has over their creation is unsettling to courts that confront the hearsay issue.<sup>32</sup>

DERs do not fit easily in any of the exceptions to the hearsay rules set forth in the Federal Rules of Evidence. They are not made by the manufacturer in the regular course of business (Rule 803(6)) but are unverified out-of-court statements to the manufacturers by other persons. They are not regularly kept records of the physician, nor are they present sense impressions under Rule 803(1) or statements of the declarant's then existing physical condition under Rule 803(2). Neither are they made

solely "for purposes of medical diagnosis or treatment and describing medical history," as required by Rule 803(4).

On the other hand, it is possible for a less demanding court to conclude that a particular DER overcomes the hearsay exception because it was compiled by a doctor as part of his medical treatment or as part of his business records. When retained by the manufacturer, a DER conceivably becomes part of its business records, and when transferred to the FDA, it becomes a public record.<sup>33</sup> The difficulty with this analysis is that a DER has no indicia of reliability at its inception, and it cannot gain reliability merely because responsible parties now possess it.

#### *D. DERs Raise Collateral Issues Regarding Collection Process*

The admissibility of DERs demands inquiry into the collection process for each DER and its similarity to plaintiff's injury, no matter whether DERs are used to show notice to the manufacturer or causation. DERs admitted into evidence must be "sufficiently similar" to plaintiff's injury so that the objections of unfair prejudice and relevancy are overcome.<sup>34</sup>

30. 115 Mich.App. 316, 320 N.W.2d 358 (1982). See also *Cosgrove*, 117 Idaho 470, 788 P.2d 1293, 1298 (DERs are clearly hearsay and not within any exception) (applying Idaho law).

31. 115 Mich.App. at —, 320 N.W.2d at 364. See *Medical Product and Drug Causation*, *supra* note 16, at 272 (discussing double hearsay issue of DERs).

32. See *Cosgrove*, 788 P.2d at 1299 ("unreliable hearsay nature"); *Richardson*, 649 F.Supp. at 801 n.5 ("anecdotal case reports" of birth defects observed in offspring of mothers whose histories included Bendectin usage and not within exception to hearsay rule).

33. It is remarkable that some courts have admitted DERs as causation evidence. In *Barson*, 682 P.2d at 839, *Squibb* argued on appeal that an exhibit including a compilation of DERs was hearsay, but the court noted that the objection made at trial was not based on the hearsay rule. The court also rejected *Squibb's* claim that experts would not rely on DERs to form opinions and seemed particularly persuaded that DERs were reliable data provided by physicians and continually monitored by the FDA. See also *Bendecton*, 624 F.Supp. 1212; *Zeck*, 559 F.Supp. at 1349 (allowing anecdotal letters in medical journals to serve as causal evidence but holding evidence insufficient as matter of law).

34. See, e.g., *Bendecton*, 624 F.Supp. at 1233, in which the court stated, on the plaintiff's motion to admit 1,200 DERs, "I will hear counsel as to whether or not selected drug experience reports may be admitted. I'm not holding that they are inadmissible in toto." See also *Cebenka*, *supra* note 1 (DERs must be sufficiently related); *Farnum v. Bristol Myers Co.*, 107 N.H. 165, 219 A.2d 277, 279 (1966) (allowing discovery of consumer complaints of similar injury before and after plaintiff's injury as evidence of causation).

Courts that demand DERs represent reliable information of sufficiently similar reactions find the task of ensuring this reliability and similarity raises collateral issues that may prolong the trial. On the other hand, allowing plaintiffs to introduce DERs en masse to show causation or even notice without regard to similarity and reliability is unfair to defendants.<sup>35</sup>

Manufacturers are required by FDA regulations to keep the identity of DER reporters and their patients confidential. This anonymity may prevent plaintiffs from establishing that DERs are accurate and sufficiently similar. The usefulness of DERs, if offered as evidence of causation, is doubtful unless the veracity of each report is demonstrated.<sup>36</sup>

#### *E. Role of Anecdotal Evidence in Forming Expert Opinion*

Even without being admitted into evidence, DERs have a potential use at trial as a basis for expert testimony. Under Federal Rule of Evidence 703 expert witnesses may rely on inadmissible evidence if it is "of a type reasonably relied upon by experts in the particular field." For those courts that demand statistically significant causation evidence, it should follow that DERs do not contribute to causation proof.

Typically, however, Rule 703 has been a low hurdle. The Judicial Conference Advisory Committee's Note to the rule cautions that, while the rule is liberal, it is not meaningless. A court, for example, would not be justified in "admitting in evidence the opinion of an

'accidentologist' as to the point of impact in an automobile collision based on statements of bystanders, since this requirement is not satisfied." A DER might be characterized as a bystander observation of an injury and nothing more than the bystander's opinion as to the cause. While an expert might rely on such a report to lead the way to scientific study, arguably an expert would not rely on DERs to form an opinion of causation.

*Barson*<sup>37</sup> is an example of a case that allowed expert testimony based on DERs. The plaintiff's expert relied in part on DERs to form an opinion that a progestational drug prescribed to a pregnant female resulted in birth defects to her child. The court remarked that DERs are "reports or observations not in evidence, made or compiled by others, [and] that experts in the FDA or elsewhere could reasonably rely on them to assist them in forming an opinion."

In *DeLuca* the Third Circuit was well aware of the serious weaknesses of the expert's theories, as viewed by other courts, but it said that those weaknesses were not an appropriate inquiry under Rule 703. "Rule 703 is satisfied once there is a showing that an expert's testimony is based on the type of data a reasonable expert in the field would use in rendering an opinion on the subject at issue; it does not address the reliability or general acceptance of an expert's methodology."<sup>38</sup>

*Cebenka v. Upjohn*<sup>39</sup> is one of the best examples of an effective use of DERs as basis for expert opinion. The expert relied on three DERs to show a cluster of contamination, the defect in the drug of which plaintiff complained. There seems little doubt that DERs would be an effective way to prove the "bad batch" effect because of the similarity between events. But while allowed as the basis for expert opinion, the DERs were excluded from evidence in *Cebenka*.

However, not all courts allow DERs to be used as part of the basis for expert opinion, recognizing that while DERs do have a place in science, they are not used to form opinions about causation but merely as early warning to potential relationships. In *Hagaman* the court concluded that DERs were not a proper basis for expert opinion on causation, stating:

As far as being the basis of an expert's opinion, the court will allow the expert to rely on the DER's only to the extent of their intended use:

35. See, e.g., *Quillen v. Int'l Playtex Inc.*, 789 F.2d 1041 (4th Cir. 1986) (excluding prior complaints of vaginal sloughing and ulcerations where plaintiff suffered from toxic shock syndrome); *Wolf v. Proctor & Gamble Co.* 555 F.Supp. 613 (D. N.J. 1982) (excluding other complaints regarding Rely tampons where plaintiff suffered from toxic shock syndrome). Cf. *Hermes*, 848 F.2d 66 (allowing DERs reporting temporary jaw disorder to establish notice of risk of permanent jaw disorder); *Savina v. Sterling Drug Inc.*, 247 Kan. 105, 795 P.2d 915 (1990) (allowing DERs reporting transitory paralysis related to myelogram to establish notice of risk of permanent paralysis).

36. In *Newsom v. Breon Laboratories*, 709 S.W.2d 559 (Tenn. 1986), the Supreme Court of Tennessee limited the disclosure of DER reporters to 12 physicians who had reported experiences with drugs involved in the litigation, protecting some 350 or 400 DERs.

37. 682 P.2d 832.

38. 911 F.2d at 953.

39. *Supra* note 1.



As an early warning method of detecting whether additional research is indicated for a specific drug. The inherent unreliability of the DER's requires this court to prohibit their use as a basis for causation. Therefore, plaintiffs' experts may, through appropriately tailored testimony, explain the impact that the DER's may have had in alerting the medical profession to possible problems with Bendectin, but the experts may not use the reports in framing a conclusion as to the teratogenicity of Bendectin.<sup>40</sup>

Barring expert reliance on anecdotal evidence is not unusual in drug product liability cases. In *In re Swine Flu Immunization Product Liability Litigation*<sup>41</sup> the Center for Disease Control determined that a causal relationship between Guillain-Barre syndrome and the swine flu vaccine could be established only when the onset of symptoms occurred within 10 weeks of inoculation. The plaintiff's symptoms presented themselves in 17 weeks, but he sought to admit anecdotal evidence of other patients diagnosed with Guillain-Barre syndrome, evidence the plaintiff's experts said would be relied on by epidemiologists. The defendant's experts, however, testified that this sort of anecdotal data would not be relied on because of the possibility of questionable diagnoses and incomplete information. The trial court determined that anecdotal evidence was not a proper basis for expert opinion on causation.<sup>42</sup>

#### DERs AS EVIDENCE OF NOTICE TO REASONABLE MANUFACTURER

The duty of a drug manufacturer is to warn of (1) dangers of which it knows and (2) dangers of which it should in the exercise of reasonable care know, if (3) those dangers are reasonably to be foreseen in the use of the drug.<sup>43</sup> The issue is whether DERs provide sufficient knowledge of a danger to obligate a manufacturer to warn the plaintiff. The manufacturer looks to the FDA to define its obligation to warn the prescribing physician and so too should the courts.

When used to show notice of a dangerous product, DERs are not hearsay since the veracity of the reports is not in question. It is appealing to assume that a company that receives reports of injuries associated with its product has received notice of a dangerous condition, but there are counter arguments to this simplistic view.

First, since DERs are not regarded as proof of a causal link between the drug and the injury, their receipt by the manufacturer arguably constitutes an early warning, not actual notice. If DERs merely raise the suspicions of a manufacturer, then perhaps a duty to investigate arises rather than a duty to warn.

Second, the FDA mandates that drug manufacturers' contraindications contain "known" and not "theoretical" hazards and that warnings be changed when "there is reasonable evidence of an association of a serious hazard," even if a "causal relationship" has not been proved. The regulations further state that "boxed warnings," those warning of a particularly serious injury, "shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data." In regard to drug interactions, the regulations require that the labeling be based on clinically significant studies and not "drug interactions supported by animal or in vitro experiments . . . unless data [are] shown to be clinically relevant."<sup>44</sup> The concern is that if labeling becomes overly cautious, warning of any potential risk or reaction, the labels may be disbelieved and ineffective.

The competing tensions at the root of the labeling requirements are to warn the product prescriber of known side effects without over-alarming physicians so that valuable drugs are underused and without over-labeling so that the labeling is discredited. Therefore, establishing notice in a product liability case should balance these public health tensions by requiring a plaintiff to show that a manufacturer had a duty to issue warnings in compliance with FDA regulations. To hold manufacturers to a higher standard contravenes the policy behind the FDA's regulations requiring credible labeling.

40. *Supra* note 6.

41. 508 F.Supp 897, *supra* note 21.

42. *See also* Agent Orange, 611 F.Supp. 1223, which is consistent. There the court did not allow affidavit checklists provided by affiant veterans to the plaintiffs' attorneys to show causation.

43. MADDEN, PRODUCTS LIABILITY 2d § 23.11 (1988). *Brown v. Superior Court* (Abbott Laboratories), 44 Cal.3d 1049, 245 Cal.Rptr. 412, 751 P.2d 470 (1988), *superceding* 227 Cal.Rptr. 768 (Cal.App. 1986), in which the California Supreme Court eliminated strict liability in all pharmaceutical cases, is an example of the growing judicial trend favoring drug manufacturers in order to protect the public's access to potentially useful drugs.

44. 21 C.F.R. §§ 201.57(d), 201.57(e) and 201.57(f)(4)(i).

Sufficient notice to give rise to the FDA's mandatory duty to warn the prescribing physician turns on "scientific notice" or a proved association between the drug and the reaction. Despite the FDA regulations, courts are inconsistent as to the level of notice required to establish the duty to warn. Although DERs do not establish causation, courts are willing to allow them for the purpose of showing notice to a manufacturer.

In *Hermes v. Pfizer Inc.*<sup>45</sup> the Fifth Circuit affirmed the admission of DERs that revealed somewhat related, although dissimilar, reactions to the drug Sinequan prior to the plaintiff's injury. The plaintiff suffered permanent "hunting jaw," allegedly as a result ingesting Sinequan. While Pfizer's warning included the possibility of temporary jaw symptoms, it asserted that it had no notice of permanent jaw injuries. The court did not adequately address this, noting instead that the jury had before it an FDA computer printout of adverse drug reaction reports concerning Sinequan, "evidence that reports of extrapyramidal symptoms were recorded as early as 1970." The court concluded that this "constructive knowledge" arose despite Pfizer's assertion that there had been no case of permanent injury shown.

The federal district court in *Skill v. Martinez*<sup>46</sup> admitted 10 of 60 DERs on the issue of defective warnings. The plaintiff, a cigarette smoker, argued that Ortho had received "a roomful" of reports of strokes associated with its contraceptive. The plaintiff also asserted that Ortho

Pharmaceutical Co. was negligent in not recording habitual smoking in its tabulations of adverse effects, and the association therefore remained undiscovered. The court said:

The report [a drug experience report] referred to in the last question was completely relevant to the issue of defective warnings since the patient had smoked one pack a day for eight (8) years and had a stroke after ingesting Ortho-Novum (Mrs. Skill smoked one-half to one pack of cigarettes a day). It was a legitimate use of this report for plaintiffs' counsel to point out to the jury that the fact that the patient had been a habitual cigarette smoker was not recorded in the Ortho tabulations. . . .

The jury was entitled to hear that Ortho did not warn about smoking and the pill even after receiving these adverse reaction reports.

The court concludes that the admission of the reports was not prejudicial and that the jury's finding that Ortho was culpable was plausible and not merely based on these three reports.<sup>47</sup>

The *Skill* court had before it ample prior scientific evidence to establish knowledge of the link between contraceptive use, smoking and strokes. It would then appear that the issue of notice and adequacy of warnings was established by scientific studies, making the DERs of little value in the trial since manufacturers are charged with "constructive notice" of scientific literature.<sup>48</sup>

Nonetheless, *Skill* points to a potentially valuable use of DERs. If a manufacturer receives "a roomful" of adverse reports and fails to analyze them properly—for example, failing to recognize the relationship among contraceptive use, smoking and stroke and thus fails to pursue scientific research to confirm the linkage—then DERs may be useful to demonstrate a failure to investigate or to behave as a reasonable manufacturer.<sup>49</sup>

In *Hermes*, on the other hand, there was a paucity of evidence on the issue of notice. In fact, the manufacturer presented evidence that the DERs offered in evidence did not represent the permanent injury of which the plaintiff complained. *Hermes*, therefore, allowed DERs to be used to establish notice of a potential event (a permanent jaw disorder) from the occurrence of a similar event (a temporary jaw disorder). The case is particularly harsh to Pfizer because Pfizer's warnings included the risk of a temporary jaw disorder.

45. 848 F.2d 66 (5th Cir. 1988). Compare *Mauldin v. Upjohn Co.*, 697 F.2d 644 (5th Cir. 1983), in which the plaintiff introduced DERs of both related and unrelated types of injuries, but the trial court provided a limiting instruction and concluded that the prejudicial nature did not influence the jury.

46. 91 F.R.D. 498 (D. N.J. 1981).

47. *Id.* at 511.

48. See, e.g., *Hermes*, 848 F.2d at 68 (whether there is duty to warn turns on manufacturer's actual knowledge, and "constructive knowledge as measured by scientific literature and other available means of communication").

49. See *Castrignano v. E.R. Squibb & Sons Inc.*, 546 A.2d 775 (R.I. 1988), in which the court stated in drug manufacturers' capacity as experts, "they must carefully monitor the new developments and research that pertain to the drugs they manufacture. This high standard of care ensures that the public will be protected from dangers as those dangers are discovered. Liability will ensue, however, if a manufacturer fails to disclose dangers of which it should have known if it had vigorously monitored available information."

*Savina v. Sterling Drug Inc.*,<sup>50</sup> much like *Hermes*, is an example of a liberal use of DERs to establish notice. The plaintiff suffered permanent paralysis following a diagnostic myelogram and asserted that the contrast agents used in the injection caused the reaction. Sterling warned only of transitory paralysis. Four DERs were alleged to establish that the manufacturer had notice that the drugs were capable of causing permanent paralysis despite the apparent improvement of patients represented in those DERs. The plaintiff's expert stated that those four cases "should have alerted Sterling Drug to the possibility of paralysis." While *Sterling* demonstrated that there was no DER indicating permanent paralysis and argued that the FDA prohibited warning of "unsubstantiated comments and concerns," the Kansas Supreme Court affirmed the use of these DERs on the issue of notice.

Several potential methods are available to manage the use of DERs for evidence of notice without forcing drug manufacturers into a Catch-22 in which they are barred by the FDA from reporting warnings because they are too speculative, yet faced with a damaging litigation weapon if they fail to act.

In *McDaniel v. Merck, Sharp & Dohme*<sup>51</sup> the Pennsylvania court remanded a product liability case against an antibiotic manufacturer, instructing the trial court to allow DERs on the issue of notice with "an expert whose testimony would explain their significance." Thus the focus might shift from the mere receipt of DERs to the proper inquiry on the issue of notice: What is the significance of the DERs, and what did the manufacturer do in response to the potential association the DERs raised?<sup>52</sup>

Unlike *McDaniel*, the court in *Worsham v. A.H. Robins*<sup>53</sup> allowed 10 DERs, which had been cleansed of "irrelevant information," to be used without expert opinion to prove notice to the manufacturer. Robins disputed the medical significance of the reports, stating that for them to be relevant, the "plaintiff would have had to introduce expert testimonial foundation showing that these documents would have had significance to a pharmaceutical company in monitoring its product." The 11th Circuit affirmed the trial court's decision to admit the evidence, stating that the issue at trial was whether Robins had received notice "sufficient to make it take action." It further concluded that the judge properly admitted the DERs with-

out expert opinion and left the sufficiency question to the jury. This is a troubling standard, for it leaves the jury to determine the "reasonable manufacturer" standard without regard to the regulations under which that manufacturer is constrained to operate.

Allowing DERs to be used to show notice without expert opinion is highly questionable. While one, two or a thousand DERs may persuade a jury that a manufacturer had notice of a danger, the receipt of DERs alone is probably insufficient notice to cause a manufacturer to change its warnings without further studies. The Bendectin cases demonstrate this. If indeed Bendectin causes no birth defects, as the courts now have generally concluded, then Merrell-Dow, despite the receipt of many DERs, had no notice of sufficient quality to justify changing its warning label. The fact that it vigorously pursued yet failed to uncover an association between drug ingestion and birth defects should establish the lack of notice, even in the face of the thousands of DERs it possessed.<sup>54</sup>

The usefulness of DERs in litigation might best be limited to answering the question of whether the manufacturer acted reasonably on the receipt of DERs. Did the manufacturer initiate further studies? Did it act promptly? Did it increase surveillance of potential associations? Did it promptly inform the FDA? In short, did the manufacturer behave as a reasonable drug manufacturer would upon the receipt of DERs? The jury should be aided by experts to answer these questions.

50. 247 Kan. 105, 795 P.2d 915 (1990).

51. 367 Pa.Super. 600, 533 A.2d 436 (1987), *appeal denied*, 520 Pa. 589, 551 A.2d 215 (1988).

52. While Hagaman, *supra* note 6, took a strong position against the use of DERs, the court postulated that they might be useful: "To the extent that the plaintiffs can produce competent evidence that defendant purposely withheld potentially damaging DER's from the public, the court believes that such use of the reports could be permissible." See also Stanton by Brooks v. Astra Pharmaceutical Prods., 718 F.2d 553, 569 (3d Cir. 1983) (allowing DERs to be used to establish negligence per se for failure to file DERs with FDA); Koller, *supra* note 5 (allowing evidence of mishandling and neglect of DERs to establish punitive damages).

53. 734 F.2d 676 (11th Cir. 1984).

54. See DeLuca, 911 F.2d 941 (detailing manufacturer's and FDA's investigation of feared association between Bendectin and birth defects); Raynor v. Richardson-Merrell Inc., 643 F.Supp. 238 (D. D.C. 1986) (describing numerous studies initiated by manufacturer).

## CONCLUSION

Drug experience reports are intended to alert drug manufacturers to the potential of undiscovered side effects from their pharmaceuticals. The current reporting system, established to safeguard public health, is regarded as underutilized and only an ancillary means of uncovering side effects after drug marketing.

Plaintiffs in drug product liability actions use DERs as evidence of causation, as the basis for expert opinion, and as evidence of the manufacturer's notice of side effects. The manufacturers argue, often effectively, that DERs are hearsay when used to establish causation or that they are irrelevant to causation analysis. They assert that anecdotal reporting is not a proper basis for expert opinion. Less successfully, manufacturers contend that DERs do not give notice of adverse side effects but are merely the impetus for studies that eventually lead to discoveries of unknown side effects.

Plaintiffs have a strong desire to use DERs, especially when their evidence of causation or notice is otherwise weak, but DERs have the potential to prejudice because juries may reach faulty conclusions about causation or may view a manufacturer as indifferent to the receipt of

DERs. Therefore, defendants have an equal stake in their exclusion. The mishandling of or indifference to the receipt of DERs may establish negligence per se, may prove constructive notice or may establish conduct supporting the imposition of punitive damages. Courts must give careful consideration to the generally unreliable nature of DERs, to their limited scientific value to the manufacturer and to the regulatory standards under which the reasonable drug manufacturer must operate.

With these factors in mind, courts should be judicious in allowing DERs to serve as evidence of either causation or notice, absent a violation of the FDA regulations or egregious conduct. In so doing, courts can most effectively balance the competing tensions in deciding the admissibility of DERs.

The liberal use of DERs in litigation represents a misuse of the reporting system. If, as the court in *Hagaman* contended, the DER reporting system is only a "red flag mechanism that could, in certain circumstances, tip off manufacturers and the medical community that a certain drug may have some contraindications," then DERs should have only limited use in litigation.